

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

FILED
RICHARD W. NAGEL
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U.S. DISTRICT COURT
SOUTHERN DIST. OHIO
EAST. DIV. COLUMBUS

IN RE APPLICATION OF THE UNITED STATES :

1)
FOR AN ORDER AUTHORIZING THE USE OF : Case No: 2:18-mj-742
UNDERCOVER OPERATIONS IN FURTHERANCE :
OF A CRIMINAL INVESTIGATION and : Magistrate Judge Deavers

2)
FOR AN ORDER OF DISCLOSURE AND : UNDER SEAL
USE OF PATIENT RECORDS

UNITED STATES' APPLICATION FOR AN EX PARTE ORDER
AUTHORIZING THE USE OF UNDERCOVER OPERATIONS AND
DISCLOSURE AND USE OF PATIENT SUBSTANCE ABUSE TREATMENT
RECORDS IN A CRIMINAL INVESTIGATION

The United States of America, by and through Assistant United States Attorney, Sal Dominguez, respectfully applies for an ex parte order pursuant to 42 U.S.C. §§ 290dd-2(b)(2)(c) and 42 C.F.R. §§ 2.66 and 2.67, for (1) an order authorizing the use of undercover operations in furtherance of a criminal investigation and (2) an order authorizing disclosure and use of patient records, to criminally prosecute a program or person holding the records, namely Dr. Freeda Flynn, 67609 Warnock Saint Clairsville Road, Saint Clairsville, Ohio 43950. Dr. Flynn is authorized to dispense controlled substances for detoxification and maintenance treatment for drug abuse patients. Such practice and its patients are extraordinarily protected by statutory restrictions relating to the disclosure and use of alcohol and drug abuse patient records.

Accordingly, the Orders requested herein are needed to obtain material evidence in a criminal investigation.

I. THE STATUTORY SCHEME FOR DISPENSING CONTROLLED SUBSTANCES FOR DETOXIFICATION AND MAINTENANCE TREATMENT

Under the provisions of the Controlled Substance Act (CSA), 21 U.S.C. §§801-971, the Drug Enforcement Administration (DEA), registers medical practitioners who dispense narcotic drugs to individuals for “maintenance treatment or detoxification treatment” 21 U.S.C. §823(g). “Maintenance treatment” is defined as the “dispensing, for a period in excess of twenty-one days, of narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drugs.” 21 U.S.C. §802(29). “Detoxification treatment” is defined as the “dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to the withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.” 21 U.S.C. §802(30).

The practitioner seeking such a registration must be qualified and abide by DEA statutes and regulations, as well as the statutes and regulations of the United States Department of Health and Human Services (HHS). 21 U.S.C. §823(g) (1). Furthermore, the applicant must be qualified and willing to “comply with the standards established by the Secretary [of HHS]...respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.” 21 U.S.C. §823(g)(1)(C). In 2000, Congress passed the Drug Addiction Treatment Act of 2000 (“DATA”), Pub. L. No. 106-310, 114 Stat. 1222 (codified at 21 U.S.C. §823(g)). Under the DATA, Congress waived the requirements under §823(g)(1) for practitioners who

dispense and administer narcotic drugs in Schedule III, IV and V (but not Schedule II) for maintenance of detoxification treatment, subject to certain conditions. 21 U.S.C. §823(g)(2)(A). Practitioners who obtain a waiver pursuant to §823(g)(2) are known as “DATA-waived physicians” or office based opioid treatment (“OBOT”) physicians. Currently, the only controlled substance approved by the Food and Drug Administration (FDA) for dispensing and administering by OBOT physicians to narcotic addicted patients is buprenorphine, the generic name for Suboxone and Subutex, a Schedule III controlled substance. 42 C.F.R. §8.12(h)(2)(iii); 21 C.F.R. §1308.13(e). In addition, the DATA limits the number of narcotic addicted patients that can be treated at one time by an OBOT physician to either 30, 100 or 275 patients. 21 U.S.C. §823(g)(2)(B)(iii). In this instance, Dr. Freeda Flynn is an OBOT physician who is allowed to treat 275 drug addicted patients pursuant to the requirements of §823(g)(2).

There are restrictions upon the disclosure and use of alcohol and drug abuse patient records “which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program” (42 C.F.R. § 2.2) such as the one under which the OBOT doctor Freeda Flynn operates. See, 42 U.S.C. § 290dd-2 and Code of Federal Regulations, Title 42, Ch. I Subch. A, Part 2, “Confidentiality of Alcohol and Drug Abuse Patient Records.” Two of several exceptions to that confidentiality is the ability of law enforcement to seek a court order to place an undercover agent or informant in the practice and to obtain patient records. See, 42 C.F.R. § § 2.66 and 2.67. This application is for such orders. Because the standards for undercover operations and record disclosures are slightly different, they are discussed separately herein and separate orders are sought.

II. APPLICATION FOR UNDERCOVER OPERATIONS

Title 42 C.F.R. §2.67(a) allows law enforcement to seek court authorization to place undercover agents or confidential sources in a drug treatment program for investigative purposes if they have “reason to believe that employees or agents of the program are engaged in criminal misconduct. The Court should issue such order upon a showing of good cause. Id. at § 2.67(c).

In order to find good cause, the court must find that:

- 1) There is reason to believe that an employee or agent of the drug treatment program is engaged in criminal activity;
- 2) Other ways of investigating the criminal activity are not available or would be ineffective, and;
- 3) The public interest and the need to place the undercover/confidential source in the treatment program outweigh the potential injury to the patients in the program, physician-patient relationships and the treatment services.

The contents of such an Order are also prescribed. It must specifically authorize the placement of “an undercover agent or informant” in the program and limit such placement to six months.

Id. at § 2.67(d). It must also prohibit such agent or informant from disclosing any patient identifying information except “as necessary to criminally investigate or prosecute employees or agents of the program.” Id. The Order should also include “any other measures which are appropriate to limit any potential disruption of the program” or breach of patient confidentiality.

Id. The example of one such measure is sealing the record of any proceeding for which disclosure of a patient’s record has been ordered. Id. The United States is requesting an Order that contains all of the required elements and sealing of the matter. As part of the instant investigation and for the reasons described in the attached Affidavit, it is necessary for law enforcement to send an undercover agent or confidential informant into practicing locations, to

determine whether the doctors, the owner of the clinic and/or employees are violating criminal laws in their billing, handling, prescribing and distribution of Suboxone (generic name Buprenorphine/naloxone) and Subutex (generic name Buprenorphine) , both are Schedule III controlled substances. Other ways to determine the existence of criminal activity would not be as effective as undercover operations. Furthermore, the public interest in determining whether there was illegal prescribing and billing of controlled substances outweighs the potential injury to the patients in the program, physician-patient relationship and the treatment services.

Notice and Opportunity for Hearing

Generally, the applicant must give notice to the “program director” of this Application and an opportunity to appear and be heard, albeit for the limited purpose of “providing evidence on the statutory and regulatory criteria for the issuance of the court order.” 42 C.F.R. § 2.67(b). However, notice and the opportunity to appear and be heard can be waived if “the application asserts a belief that:

- (1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or
- (2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.” Id.

The “program director,” as defined in 42 C.F.R. § 2.11 is the individual (if the program itself is an individual) or the individual designated as director, managing director or “otherwise vested with authority to act as chief executive of the organization” (if the program is an entity.) Given the definitions of “program”, also found in § 2.11, it appears that Freeda Flynn holds herself out as providing “drug abuse diagnosis, treatment or referral for treatment” and is thus a program director. Since the attached Affidavit and this Application reveal suspicions that Dr. Flynn is involved in the criminal activities that are being investigated, it is likely that she will

intentionally disclose the proposed placement to any other employee suspected of criminal activities. The United States thus requests that such notice be waived.

III. APPLICATION FOR CONFIDENTIAL PATIENT RECORDS

Under 42 U.S.C. §290dd-2(a), “ records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated or directly or indirectly assisted by any department or agency of the United States shall....be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.”

Under 42 U.S.C. §290dd-2(b)(2)(C), confidential records as described above in §290dd-2(a), may not be disclosed to law enforcement personnel unless “authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefore....” That statute continues by explaining, “[i]n assessing good cause the court shall weigh the public interest and the need for disclosure against injury to the patient , the physician-patient relationship, and to the treatment services.”

The United States must obtain an “order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute a program or the person holding the records (or employees or agents of that program or person).” 42 C.F.R. 2.66(a)(1). Such an order “may be applied for by any administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the program’s or person’s activities.” *Id.* In this case, the applicant has jurisdiction to prosecute the criminal violations to be investigated.

Under 42 C.F.R. §2.66(a)(2), “[t]he application may be filed separately or as a part of a pending civil or criminal action against a program or the person holding the records...in which it appears that the patient records are needed to provide material evidence.” A disclosure order “may be entered only if the court determines that good cause exists.” 42 C.F.R. § 2.66(c) and § 2.64(d). To make this determination the court must find that:

- (1) Other ways of obtaining the information are not available or would not be effective; and
- (2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services. (Id.)

Further, the content of a disclosure must “(1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order; (2) Limit disclosure to those persons whose need for information is the basis for the order; and (3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.” 42 C.F.R. § 2.64(e). This application seeks a court order that fulfills all of the mandates of the applicable statutes and regulations as to disclosure of patient records and a sealing of this Application, Affidavit and Court Order.

When conducting substance abuse investigations, obtaining material evidence from patients that are recovering drug addicts is difficult because generally substance abuse patients do not want to cooperate with law enforcement by consenting to the use and disclosure of their patient records. Furthermore, patients will often notify the specific individuals being investigated of law enforcement's inquiries. Such premature notification can have an adverse effect on the investigation. Thus, other ways of obtaining the information are not available or

would not be effective; and, as shown in the attached Affidavit, the public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

Notice and Opportunity for Hearing

An application for patient records for a criminal investigation may be granted without notice in the Court's discretion. 42 C.F.R. § 2.66(b). In this case, notice should not be given of the request to seek patient records as such notice is inconsistent during a proposed undercover operation in a criminal investigation. Notice of the application may result in the destruction, removal or tampering with patient records and the United States thus requests that no notice of the application be given.

Although no express notice is required "to the program, to the person holding the records, or to any patient whose records are to be disclosed", each of those must be given the opportunity to seek revocation or amendment of the order. 42 C.F.R. § 2.66(b). That opportunity does not arise, however, until the Order is implemented. Id. So, for example, if the United States proceeds with the undercover investigation and gets to the point that it has probable cause to seek a search warrant¹ for patient records, the Order being requested now would be "implemented" at that time. As with the hearing for the undercover operation, the opportunity afforded is only to "seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order." Id.

¹ Even a Grand Jury subpoena would require an order like the one currently being requested

IV. REQUESTED ORDERS

In order to conduct the investigation, the United States is requesting two orders from this Court. One authorizing an undercover investigation as contemplated by 42 C.F.R. § 2.67 and one authorizing the disclosure and use of patient records as contemplated by 42 C.F.R. § 2.66.

A. Order Authorizing Undercover Investigation

Based on the facts summarized herein and set forth more particularly in the attached Affidavit, there is reason to believe that employees or agents of the program are engaged in criminal misconduct. 42 C.F.R. § 2.67(a) and (c). There is good cause to issue the orders since other ways of investigating the criminal activity are not available or would be ineffective, and the public interest and the need to place the undercover/confidential source in the treatment program outweigh the potential injury to the patients in the program, physician-patient relationships and the treatment services. See 42 C.F.R. § 2.67(c). The proposed Order incorporates the required contents as set forth in 42 C.F.R. § 2.67(d).

Further, no notice should be given to the “program director” because it is believed that such person or persons are either involved in the criminal activities or will intentionally or unintentionally disclose the proposed undercover investigation to suspects. 42 C.F.R. § 2.67(b)(1) and (2).

Accordingly, the United States requests that the proposed Order be granted and that this Application, its supporting Affidavit and the Court’s Order be sealed until further order of this Court.

B. Order Authorizing Disclosure and Use of Patient Records

Because the applicant is a law enforcement or prosecutorial agency having jurisdiction of the potential crimes being investigated and because the records are needed to provide material evidence, this Court should issue the proposed Order for disclosure and use of patient records. 42 C.F.R. § 2.66(a)(1) and (2). There is good cause to issue the proposed Order since other ways of investigating the criminal activity are not available or would be ineffective, and the public interest and the need to place the undercover/confidential source in the treatment program outweigh the potential injury to the patients in the program, physician-patient relationships and the treatment services. See 42 C.F.R. §§ 2.66(c) and 2.64(d). The proposed Order incorporates the required contents as set forth in 42 C.F.R. §§ 2.66(c) and 2.64(e).

Records may be in the custody of: state or federal agencies or private insurance companies any one of which may pay for prescriptions or treatment; boards or other administrative agencies with oversight of the Suboxone program or physicians generally; third party billing companies; Dr. Freeda Flynn, her employees, owner, doctors or contractors; or patients themselves. The records may contain evidence of diversion of buprenorphine, identify victims of the crimes being investigated and identify witnesses. The Order will be disclosed to the appropriate party each time it is implemented so that the appropriate party has an opportunity to seek revocation or amendment as limited by regulation. 42 C.F.R. § 2.66(b) Other than that disclosure, the United States is not required to give notice and requests that this Application, its supporting Affidavit and the Court's Order be sealed until further order of this Court.

Further, disclosure of the records will be limited to employees of the DEA, the Ohio State Board of Pharmacy (OSBP), the State Medical Board of Ohio (SMBO), the Ohio Attorney

General's Medicaid Fraud Control Unit (MFCU), Health and Human Service (HHS), Federal Bureau of Investigation (FBI), Bureau of Workers Compensation (BWC), United States Attorney's Office, other federal or state law enforcement personnel, and retained experts. The United States will also maintain control of the medical records as required by all relevant regulations and statutes. No information obtained pursuant to this request will be used to conduct any investigation or prosecution of a patient for seeking treatment for drug addiction, nor will it be used as the basis for an order under 42 C.F.R. § 2.65, in accordance with 42 C.F.R. § 2.66(d)(2).

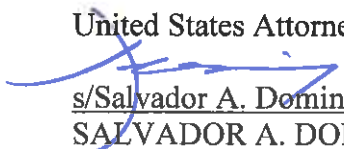
Any patient identifying information, as defined in 42 C.F.R. § 2.11, will be deleted from any documents made available to the public, in accordance with 42 C.F.R. § 2.66(d)(1), absent further order of this Court or appropriate waivers or consents

CONCLUSION

For all of the foregoing reasons, the proposed Orders attached hereto should be granted.

Respectfully submitted,

BENJAMIN C. GLASSMAN
United States Attorney


s/Salvador A. Dominguez
SALVADOR A. DOMINGUEZ (0056232)
Assistant United States Attorney
303 Marconi Boulevard, Suite 200
Columbus, Ohio 43215
Office: (614) 469-5715
Fax: (614) 469-2769
E-mail: Sal.dominguez@usdoj.gov

AFFIDAVIT IN SUPPORT OF THE UNITED STATES' APPLICATION FOR AN EX PARTE ORDER AUTHORIZING THE USE OF UNDERCOVER OPERATIONS AND DISCLOSURE AND USE OF PATIENT SUBSTANCE ABUSE TREATMENT RECORDS

1. I, William D. Crawford, am a Diversion Investigator with the Drug Enforcement Administration (DEA) and am currently assigned to the Columbus Division Office Tactical Diversion Squad (TDS). I have been employed as a Diversion Investigator for three years. Prior to my employment with the DEA I served 27 years with Hoover Police Department in Hoover, Alabama, the last 15 years of which I was assigned to the Special Investigation Unit. During this time, I was involved in many different types of criminal investigations to include drugs, conspiracy, money laundering, gun violations, human trafficking and child exploitation. I submit this affidavit in support of an application for an order authorizing the use of surveillance and undercover operations as well as for an order for disclosure and use of patient records. The information contained in this affidavit is either known to me through my own investigation or from information shared with me by other law enforcement and regulatory agency investigators, to include personnel from the Drug Enforcement Administration and the State of Ohio Board of Pharmacy (SOBP).

2. The Columbus, Ohio DEA TDS received information that Dr. Freeda Flynn, DEA #BF4011831, located in Saint Clairsville, Ohio, is suspected of improperly prescribing opioids, which are schedule II controlled substances; Suboxone (buprenorphine/naloxone) and Subutex (buprenorphine), both are schedule III controlled substances; as well as various benzodiazepines, which are schedule IV controlled substances.

3. On May 23, 2018 Diversion Investigators DeAndra Lee and Sandra McMillian from the Charleston, West Virginia District Office of DEA received information from a pharmacist in Moundsville, West Virginia that Dr. Freeda Flynn had unusual prescribing habits including the excessive prescribing of Xanax (a benzodiazepine) and leaving the patients on the same dose of the same medication for extended periods of time. The pharmacist also stated that Flynn is a pain management doctor that also has an Office Based Opioid Treatment (OBOT) practice.
4. On May 22, 2018 and May 25, 2018, Diversion Investigator William D. Crawford received information from two different pharmacists in Jefferson and Belmont counties in Ohio that Dr. Freeda Flynn was believed to be over prescribing Xanax and other benzodiazepines. That information also revealed that Dr. Flynn was prescribing Xanax and other benzodiazepines to patients being prescribed Suboxone or Subutex to treat opioid drug addiction. It should be noted that the Substance Abuse and Mental Health Services Administration (SAMHSA) warns practitioners against prescribing benzodiazepines along with Suboxone or Subutex during addiction treatment due to the chances of overdose or diversion. SAMHSA also warns against the prescribing of Subutex rather than Suboxone to patients due to the increased potential of diversion. Due to the fact Subutex does not contain naloxone it is often diverted for abuse by injection. SAMHSA advises practitioners to restrict the prescribing of Subutex to female patients who are pregnant or will potentially become pregnant; patients with a documented allergy to naloxone; and to those with hepatitis or HIV.

5. On September 4, 2018 Investigator Crawford met with investigators from the Ohio State Board of Pharmacy (OSBP). The OSBP investigators stated that the OSBP had received complaints from Belmont County Drug Task Force stating that Flynn's prescribing habits were questionable. OSBP also interviewed a confidential informant from Belmont County Drug Task Force who stated that BB, a male patient of Flynn's, was being prescribed Suboxone for drug addiction treatment and was also receiving prescriptions from Flynn for clonazepam, a benzodiazepine. In addition, BB's wife, TB, was also receiving prescriptions from Flynn for clonazepam. TB is known to sell clonazepam on the street.

6. After the conclusion of the meeting Investigator Crawford reviewed an Ohio Automated Rx Reporting System (OARRS) report of the past two years of Flynn's prescribing. The report verified that Flynn did prescribe benzodiazepine drugs along with Suboxone or Subutex. The report confirmed that in the past two years BB received prescriptions for Suboxone along with lorazepam, diazepam and clonazepam, all of which are benzodiazepines that are commonly diverted for sale on the street. The report also indicated that Flynn prescribed TB clonazepam nine times in the past seven months. In addition to BB and TB, the OARRS report showed that there were several instances where Dr. Flynn prescribed the same or similar opioids or benzodiazepines to multiple members of the same family. The OARRS report also showed that Flynn prescribed patients opioids including oxycodone and fentanyl along with Suboxone or Subutex, which is prescribed to treat opioid addiction. In addition, Flynn prescribed both long acting and immediate release opioids to patients, some of which also received benzodiazepines. Flynn also prescribes Subutex, rather than Suboxone, to several male patients. All of these are known indicators

of diversion. Lastly, Flynn has numerous patients that travel one to two hours by motor vehicle to see her and receive prescriptions.

7. Based on these allegations, the DEA, SOBP, and the Ohio Attorney General, Health Care Fraud Section have opened investigations of Dr. Freeda Flynn for possible violations of 21 U.S.C. § 846 (conspiracy to distribute drugs); 21 U.S.C. § 841(a) (1) (illegal drug distribution); and other violations of state and federal law.


William D. Crawford
Diversion Investigator, Drug Enforcement Administration

Subscribed and sworn to before me

This 28 day of September, 2018.


UNITED STATES MAGISTRATE JUDGE DEEVERS

